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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,271

04/02/2004

Max Allen Weaver

32887-297395

1783

7590

10/03/2006

Charles W. Calkins  
Kilpatrick Stockton LLP  
1001 West Fourth Street  
Winston-Salem, NC 27101

EXAMINER

KOSACK, JOSEPH R

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/817,271	WEAVER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph Kosack	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 59,60 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 59,60 and 63-68 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

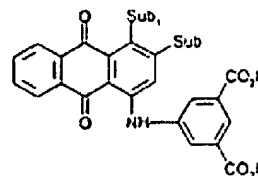
Claims 59-60 and 63-68 are pending in the instant application.

#### *Election/Restrictions*

The Markush Group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, which are too numerous to list individually. **For the reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. § 121**, wherein a Group is a set of patentable distinct inventions of a broad statutory category (e.g. compounds, methods of use, methods of making, etc.):

- I. Claim 59 (in part), drawn to compounds of formula XIV, classified in various subclasses of class 540, 544, 546, 548, and 549.
- II. Claim 59 (in part), drawn to compounds of formula XIXc, classified in various subclasses of class 540, 544, 546, 548, and 549.
- III. Claim 59 (in part), drawn to compounds of formula XIXd, classified in various subclasses of class 540, 544, 546, 548, and 549.
- IV. Claim 59 (in part), drawn to compounds of formula XIXe, classified in various subclasses of class 540, 544, 546, 548, and 549.
- V. Claim 59 (in part), drawn to compounds of formula XIXf, classified in various subclasses of class 540, 544, 546, 548, and 549.

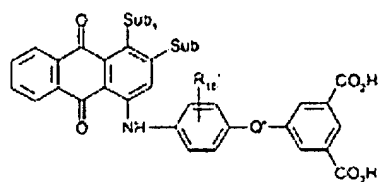
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VI. Claim 60 (in part), drawn to compounds of formula

classified in various subclasses of class 540, 544, 546, 548, and 549.

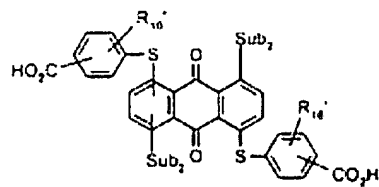
VII. Claim 60 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

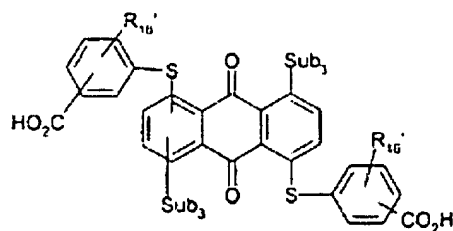
VIII. Claim 63 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

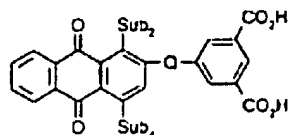
IX. Claim 63 (in part), drawn to compounds of formula



, classified in various subclasses of

class 540, 544, 546, 548, and 549.

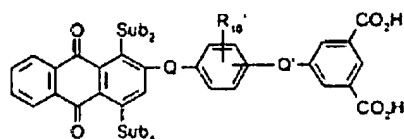
X. Claim 64 (in part), drawn to compounds of formula



, classified in various subclasses of class 540,

544, 546, 548, and 549.

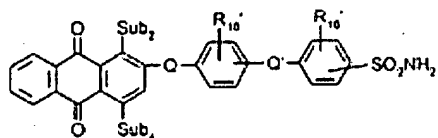
XI. Claim 64 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

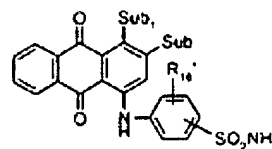
XII. Claim 64 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

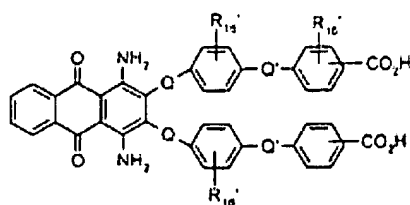
XIII. Claim 65, drawn to compounds of formula



classified in various subclasses of class 540, 544, 546, 548, and 549.

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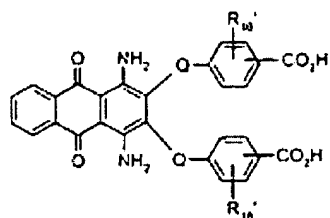
XIV. Claim 66 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

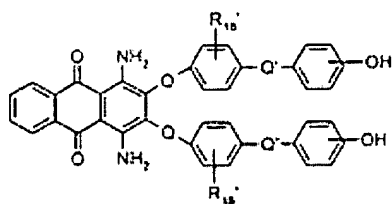
XV. Claim 66 (in part), drawn to compounds of formula



, classified in various subclasses of class 540,

544, 546, 548, and 549.

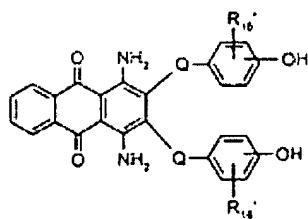
XVI. Claim 66 (in part), drawn to compounds of formula



, classified in various subclasses of class

540, 544, 546, 548, and 549.

XVII. Claim 66 (in part), drawn to compounds of formula

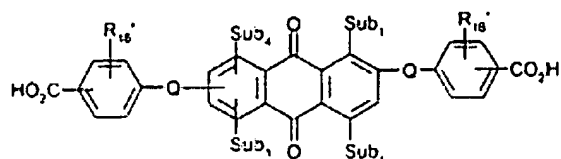


, classified in various subclasses of class 540, 544,

546, 548, and 549.

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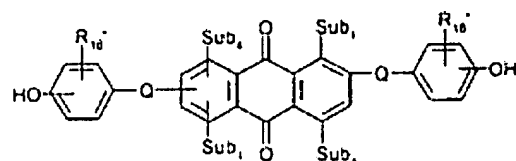
XVIII. Claim 67 (in part), drawn to compounds of formula



, classified in various

subclasses of class 540, 544, 546, 548, and 549.

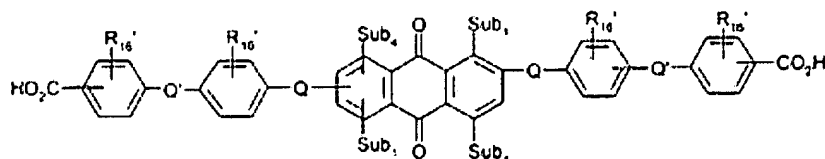
XIX. Claim 67 (in part), drawn to compounds of formula



, classified in various subclasses of

class 540, 544, 546, 548, and 549.

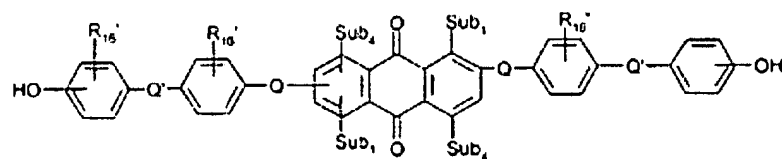
XX. Claim 67 (in part), drawn to compounds of formula



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various subclasses of class 540, 544, 546, 548, and 549.

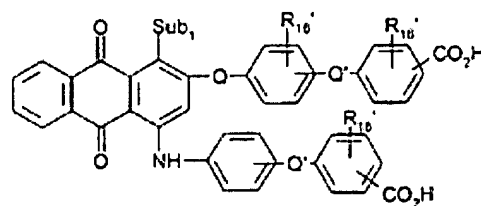
XXI. Claim 67 (in part), drawn to compounds of formula



, classified in

various subclasses of class 540, 544, 546, 548, and 549.

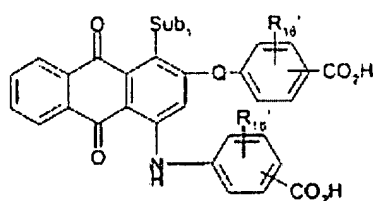
XXII. Claim 68 (in part), drawn to compounds of formula



, classified in various subclasses of

class 540, 544, 546, 548, and 549.

XXIII. Claim 68 (in part), drawn to compounds of formula



, classified in various subclasses of class 540,

544, 546, 548, and 549.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush Group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush Group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. § 103.

**Where an election of Groups I-XXIII is made, an election of a single compound is further required** including an exact definition of each substitution on the



base molecule wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group  $R_{14}$ , wherein  $R_{14}$  is recited to be any one of hydrogen, halogen, phenyl, etc... then Applicant must select a single substituent of  $R_{14}$ , for example hydrogen, and each subsequent variable position, i.e. Q, Q', Sub, Sub<sub>1</sub>, etc...

In the instant case, upon election of a single compound the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds that are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses.

Examination will then proceed on the elected compound as defined by common classification AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identity such evidence now of record

showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in rejection under 35 U.S.C. § 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. § 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. § 121 apply with regard to double patenting covering divisional applications.)

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

If desired upon election of a single compound, applicant can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar, within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

***Rational Establishing Patentable Distinctiveness Within Each Group***

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are presumed patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to be function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch***, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and ***In re Lalu***, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

***The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:***

Inventions I through XXIII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have various different substituents attached to the base anthraquinone group, giving them a materially different design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

In addition, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

#### ***Advisory of Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Charles Calkins on September 20, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

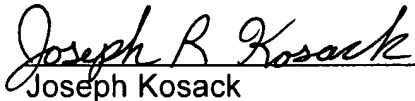
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph Kosack  
Patent Examiner  
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Joseph K. McKane  
Supervisory Patent Examiner  
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